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FILED
 Superior Court of California
 County of Los Angeles

OCT 23 2017

Sherri R. Carter, Executive Officer/Clerk

By Nancy Alvarez Deputy

**SUPERIOR COURT OF THE STATE OF CALIFORNIA
 IN AND FOR THE COUNTY OF LOS ANGELES**

BC 680843

EMILY ELSON, STACY HAAVISTO,
 LORETTA OAKES, MICHELLE
 LANUM, JULIA LEFEBVRE, SUE
 GRICKY, TILLY DORENKAMP,
 DINA SALAS, ARLENE RODRIGUEZ,
 JERRY GAINES, and all others
 similarly situated,

Plaintiffs,

vs.

ASHLEY BLACK, an individual,
 ASHLEY DIANA BLACK
 INTERNATIONAL HOLDINGS, LLC,
 a Delaware Corporation, ADB
 INTERESTS LLC, a Texas Corporation,
 and DOES 1-100,

Defendants.

CASE NO. _____

CLASS ACTION COMPLAINT FOR:

1. FALSE ADVERTISING (CAL. CIV. CODE § 1770)
2. STRICT PRODUCT LIABILITY – DESIGN DEFECT
3. STRICT PRODUCT LIABILITY – FAILURE TO WARN
4. NEGLIGENCE
5. NEGLIGENCE PER SE
6. GROSS NEGLIGENCE
7. RECKLESS MISCONDUCT
8. BREACH OF EXPRESS WARRANTY
9. BREACH OF IMPLIED WARRANTY: FITNESS FOR PARTICULAR PURPOSE
10. BREACH OF IMPLIED WARRANTY: MERCHANTABILITY
11. DECEIT/INTENTIONAL FRAUD
12. DEFAMATION
13. INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS
14. UNFAIR BUSINESS PRACTICES (CAL. BUS. & PROF. CODE §§ 17200 *et seq.*)
15. FALSE ADVERTISING (CAL. BUS. & PROF. CODE §§ 17500 *et seq.*)

JURY TRIAL DEMANDED

CITY/CASE: BC680843
LEA/DEF#:

RECEIPT #: CCH451233096

DATE PAID: 10/23/17 04:07 PM

PAYMENT: \$1,435.00

RECEIVED:

CHECK:	\$0.00
CASH:	\$0.00
CHANGE:	\$0.00
CARD:	\$1,435.00

310

1 Plaintiffs Emily Elson, Stacy Haavisto, Loretta Oakes, Michelle Lanum, Julia
2 Lefebvre, Sue Grlicky, Tilly Dorenkamp, Dina Salas, Arlene Rodriguez, and Jerry
3 Gaines ("Plaintiffs") on their own behalf and on behalf of all others similarly
4 situated, bring this action for injunctive relief and for damages under the laws of the
5 State of California.

6 **I. INTRODUCTION**

7
8 1. Defendants Ashley Black ("Black"), Ashley Diana Black International
9 Holdings, LLC, Adb Interests, LLC, and DOES 1-100 (collectively "Defendants")
10 manufacture, test, market, endorse, distribute and/or sell a putative medical device
11 called "FasciaBlaster" which not only (a) did and does fail to deliver the aesthetic
12 results stridently guaranteed by Defendants' false and deceptive advertising, but
13 which moreover (b) did and does cause a wide array of physical injuries exemplified
14 by the experiences of the Plaintiffs, running the gamut from simply worsening the
15 aesthetic conditions which the device is supposed to improve, to far more severe
16 harms such as extreme hormonal instability, stroke, and others described herein.
17 Furthermore, when some of the Plaintiffs justifiably discussed their dangerous and
18 scary FasciaBlaster experiences within Internet social media forums, hoping to find
19 answers and to help minimize the risks to others, Defendants responded with (c)
20 censorship and a vicious, vindictive campaign of orchestrated defamation,
21 harassment, cyber-bullying, intentional infliction of emotional distress, and
22 malicious prosecution.

23 2. Currently selling for \$89, the FasciaBlaster is ostensibly a massage
24 'stick' with handles on both ends and a set of hard plastic claws¹ protruding from

25
26 ¹ Various versions of the device, differing mainly in size, are advertised for
27 use on different parts of the body, e.g. "FaceBlaster," however all versions have the
28 central 'claw' features in common, and all are marketed as operating on roughly the
(footnote continued)

1 the middle. Its damage is done when a user follows Defendants' marketing and
2 instructional materials' direction: first, to heat up the target area of the body e.g. in a
3 sauna, then to strenuously, painfully rake² the claws over one's heated skin.
4 Defendants direct users to 'blast' at a pain level of "7 out of 10" in pursuit of a
5 laundry list of exciting results promised by Defendants, including cellulite
6 reduction, improved skin tone and muscle definition, and other health and beauty
7 benefits. Some FasciaBlaster marketing assertions, e.g. that 'blasting' relieves
8 symptoms of Multiple Sclerosis and Parkinson's disease, or that it is "completely
9 safe for children!" are particularly galling. And of course, Defendants assert that
10 said benefits are all the more likely when one also purchases from their line of
11 approved FasciaBlaster accessories, including expensive skin creams and oils for
12 use with the device.

13 3. In addition to the foregoing false advertising, Defendants did and do
14 make deceptive public representations e.g. regarding U.S. Food and Drug
15 Administration ("FDA") approval of the FasciaBlaster, regarding the scientific
16 testing their devices have undergone, and regarding the academic and medical
17 credentials of multiple agents and employees whom Defendants did and do feature
18 prominently in FasciaBlaster advertising and instructional materials.

19 4. On information and belief, Defendants have long known that
20 FasciaBlaster can be dangerous, but instead of issuing a recall or ceasing to sell the
21 devices, they have persevered in commerce largely indifferent to the harms the

22
23 same principle via the same general type of usage, i.e. aggressive self-massage over
24 targeted connective tissue. As such, to avoid confusion this Complaint refers to all
25 versions of the device under the umbrella term "FasciaBlaster" except where a
distinction between versions may be pertinent for e.g. narrative purposes.

26 ² 'Blasting' is the vernacular term Defendants use in their marketing and
27 instructional materials, and which Plaintiffs adopt herein, as shorthand for the
28 directed use of the FasciaBlaster.

1 device did and will continue to cause. Instead of real accountability, Defendants
2 occasionally make mere minor adjustments to their marketing or directions for
3 use—presenting an air of authority while offering meaningless bromides such as
4 “blast for 5 minutes instead of 10” and “use less heat first”—along with the
5 aforementioned deliberate and callous campaign of intimidation against their
6 dissatisfied and/or injured customers.

7 5. The named Plaintiffs, along with all others similarly situated, were
8 taken in and victimized by Defendants’ deceptive business practices. Each named
9 Plaintiff, and others similarly situated, has suffered as a result of Defendants’
10 negligence, gross negligence, recklessness, and fraud in the manufacture, testing,
11 marketing, endorsement, distribution, and sale of a dangerous device with directions
12 for dangerous use coming from Defendants’ medically unqualified and incompetent
13 spokespeople. For product liability purposes, the proposed Plaintiff class may be
14 divided into subclasses based on the array of physical maladies attributable to
15 FasciaBlaster which the various named Plaintiffs have suffered, as detailed herein.
16 For example, Plaintiffs may ultimately seek to certify e.g. Subclass A consisting of
17 individuals who have suffered endocrine problems; Subclass B consisting of
18 individuals who have suffered cardiovascular problems; Subclass C consisting of
19 individuals who have suffered digestive problems; Subclass D consisting of
20 individuals who have suffered neurological problems; Subclass E consisting of
21 individuals who have suffered psychological problems; Subclass F consisting of
22 individuals who have suffered defamation, harassment, or cyber-bullying; and
23 Subclass G consisting of individuals who have suffered from aesthetic harms, e.g.
24 the worsening of cellulite or wrinkles after use of a FasciaBlaster purchased and/or
25 used based on Defendants’ aggressive representations that it would have precisely
26 the opposite effect. This Court is asked to expeditiously and actively enforce the
27 many laws at issue, in order both to provide redress for the physical injuries already
28

1 suffered and to prevent countless such injuries from continuing to occur in the
2 future.

3 **II. JURISDICTION**

4 3. Plaintiffs Elson and Haavisto are residents of Los Angeles County.

5 4. The Defendants include an individual—Ashley Black—who on
6 information and belief resides in Los Angeles County, whom the Plaintiffs hereby
7 sue in her personal capacity for acts and omissions by her (for both monetary and
8 nonmonetary³ purposes) and because two other Defendants, corporations of which
9 she is President, sole or controlling shareholder, or otherwise principal, qualify as
10 her alter egos on information and belief, justifying the Court in piercing corporate
11 veils.

12 5. Further, this Court has personal jurisdiction over the Defendants hereto
13 because any Defendants which are not California residents are nevertheless subject
14 to California's long-arm statute by virtue of *inter alia* the fact that they avail
15 themselves of the protection of California law in their commercial dealings in
16 California's marketplace, which dealings are ample and the subject of this lawsuit.
17 Specifically, the Defendants advertise and promote use of their products to potential
18 customers in California via e.g. the Internet, television, and in print, and sell their
19 products in California via e.g. online purchase or mail-order. The foregoing
20 constitutes well more than the minimum commercial contacts with California
21 necessary to provide this Court with personal jurisdiction over Defendants pursuant
22 to *Fireman's Fund Ins. Co v. National Bank of Cooperatives*, 103 F.3d 888, 893 (9th
23 Cir. 1996) and *International Shoe Co. v. Washington*, 326 U.S. 310, 316 (1945).

24
25
26 ³ Defendant Black relishes her status as a self-designated celebrity health
27 "guru," providing her with personal, nonmonetary egocentric benefits subject to
28 proof, above and beyond the personal and corporate financial rewards of her actions.

III. PARTIES**DEFENDANTS**

6. On information and belief, Defendant Ashley Black is an individual living in Manhattan Beach, California. On information and belief, Black is the President, CEO, principal, majority shareholder, or only shareholder of both Ashley Diana Black International Holdings, LLC and Adb Interests, LLC. On information and belief, there are grounds on which this Court may find that said corporations are Black's alter egos, and pierce one or both corporate veils as appropriate to hold her personally liable for their acts and omissions.

7. Defendant Ashley Diana Black International Holdings, LLC ("ADBIH") is a Delaware limited liability company headquartered, on information and belief, in Pearland, Texas. On information and belief, ADBIH is a close corporation controlled by, and qualifying as an alter ego of, Defendant Ashley Black. On information and belief, ADBIH was incorporated to own/manage intellectual property, i.e. trademarks and patents pertaining to the device(s) known as FasciaBlaster and assorted accessories for use therewith. Other than the foregoing corporate functions, the full and precise nature of ADBIH's relationship with the other Defendants is unknown at this time, and Plaintiffs will seek leave of Court to amend this description if necessary after discovery.

8. Defendant Adb Interests, LLC ("ADBI") is a Texas limited liability company headquartered, on information and belief, in Pearland, Texas. On information and belief, ADBI is a close corporation controlled by, and qualifying as an alter ego of, Defendant Ashley Black. On information and belief, ADBI produces, promotes, and sells FasciaBlaster devices and the assorted accessories sold for use therewith; on information and belief, ADBI does business as ADB Innovations LLC for purposes of distributing the skin creams and oils. Other than the foregoing, the full and precise nature of ADBI's relationship with the other

1 Defendants is unknown at this time, and Plaintiffs will seek leave of Court to amend
2 this description if necessary after discovery.

3 9. At this time, the true names and capacities—individual, corporate,
4 associate or otherwise—of Defendants DOES 1 through 100, inclusive, are
5 unknown to Plaintiffs, who thus sue said DOES by such fictitious designation until
6 such time as Plaintiffs are adequately informed about them, including *inter alia* their
7 respective degrees of and reasons for personal liability, to seek leave of the Court to
8 amend this Complaint to include their true names. On information and belief, each
9 of the DOE Defendants bears some degree of liability to Plaintiffs, and others
10 similarly situated, for the unlawful acts and omissions described herein.

11 **PLAINTIFFS**

12 10. Each of the Plaintiffs named herein purchased and/or used
13 FasciaBlaster, and between them they suffered a wide variety of severe harms
14 therefrom as described herein.

15 **A. Emily Elson**

16 11. Emily Elson (“Elson”), age 40, is an individual who resides in Los
17 Angeles, California. Elson first purchased a FasciaBlaster device in or around
18 March of 2017 because she saw advertising—on social media website Facebook—
19 which touted the device’s ability to reduce cellulite. Elson then ‘blasted’ as directed
20 by Defendants’ marketing and instructional materials, i.e. raked the device over her
21 heated skin, all over her body except for her head, neck, and face, approximately
22 once per week for a mere four or five weeks, before stopping when a host of
23 physical ailments began to arise.

24 12. Elson has been and is planning to undergo artificial insemination. As of
25 early 2017, in light of her teaching schedule she planned to undergo the procedure in
26 June or July of 2017 (in order that her maternity leave at the end of the Spring 2018
27 semester would lead into her Summer break, allowing her to devote maximum time
28

1 to infant care and bonding) without unduly delaying the attempt beyond the already
2 fraught, well-known 40-years' benchmark. According to ample research (subject to
3 proof), after 40 years of age, women find e.g. fertilization more difficult to achieve,
4 egg quality degraded, egg numbers reduced, and that the risk of birth defects
5 increases significantly. In order to maximize her odds of conceiving a healthy baby,
6 Elson diligently underwent regular testing to monitor her reproductive hormone
7 levels, including *inter alia* Follicle-Stimulating Hormone ("FSH"), and Luteinizing
8 Hormone ("LH"), Progesterone, and Estrogen. Blood tests taken shortly before she
9 began 'blasting' showed all of the foregoing hormones within better-than-average
10 ranges. Prior to the events described herein, Elson had last undergone a test for Anti-
11 Mullerian Hormone ("AMH" which indicates 'ovarian age,' i.e. overall fitness for
12 fertilization) at age 38, at which time her AMH levels were optimal.

13 13. After 'blasting' for only a short period in or around March of 2017,
14 Elson became very ill. She is a carrier of the Epstein-Barr virus, and had
15 successfully managed that condition with *inter alia* natural supplements, keeping
16 'flare ups' at bay for approximately two years before she began 'blasting.'
17 Immediately after 'blasting,' however, she experienced an abrupt, aggressive and
18 painful flare up of Epstein-Barr virus symptoms, persisting to the date hereof. On
19 information and belief, 'blasting' released and reactivated dormant virus cells which
20 had previously been trapped benignly within e.g. subcutaneous fat cells, a
21 conclusion which Elson and multiple health practitioners later reached after *inter*
22 *alia* learning about other FasciaBlaster users' having had the same experience with
23 cases of 'reactivated' Epstein-Barr, Shingles, Lyme disease, etc.

24 14. In addition to the foregoing, promptly after 'blasting' Elson began to
25 experience intense menstrual and other unusual hormonal side-effects, different in
26 nature and severity than any variations she had previously experienced. Her next
27 round of reproductive hormone laboratory testing, undertaken within 6 weeks after
28

1 'blasting,' revealed dramatic changes compared to the preceding test results, well
2 beyond typical fluctuations: her FSH and LH levels had roughly doubled, while her
3 Progesterone level dropped precipitously. Her Estrogen levels swung wildly,
4 dropping at first before spiking well above February (pre-'blasting') levels. Further,
5 her AMH level had plummeted well below expectations, suddenly indicating
6 "compromised fertility." As any aspiring mother would be under these
7 circumstances, Elson was emotionally devastated⁴ by these results.

8 15. Beyond the foregoing illnesses, pain, hormonal swings, and emotional
9 distress Elson suffered as a result of her 'blasting,' the appearance of cellulite which
10 she had sought to reduce instead became—and remains—significantly more
11 conspicuous.

12 **B. Stacy Haavisto**

13 16. Stacy Haavisto ("Haavisto") is an individual who lives in Los Angeles,
14 California. She uses Facebook daily, and was subject to aggressive targeted
15 FasciaBlaster advertising thereon. Desiring to reduce cellulite and lose weight, she
16 gave in to the targeted ads and purchased her first FasciaBlaster in or around April
17 of 2016. She promptly began 'blasting' approximately five times per week for
18 approximately three months, then more sporadically until ceasing to 'blast' in ~~March~~
19 ~~or April~~ of 2017. She ultimately spent roughly \$500 on various FasciaBlaster ~~March~~
20 devices and accessories.

21
22 ⁴ Elson's low AMH level was especially upsetting because, ordinarily, AMH
23 levels only ever decrease over time; significant AMH increases are extremely rare.
24 Elson was thus very fortunate when, after 10+ weeks of depression and anxiety
25 following her "compromised fertility" result, her next AMH test—between four and
26 five months after she had ceased 'blasting' once and for all—showed surprising
27 improvement. Although AMH decrease between ages 38 and 40 is normal, Elson
28 attributes the circumstance to the FasciaBlaster on information and belief because
the significant AMH *increase*, months later, is extraordinarily unusual.

1 17. From the beginning, 'blasting' would cause Haavisto to feel foggy-
2 headed, lethargic, and physically fatigued. She grew more and more ill, suffering
3 constipation, Irritable Bowel Syndrome, gas pains, heart palpitations, insomnia,
4 anxiety, difficulty concentrating, blurred vision, vertigo, and severe headaches every
5 day upon waking. Adding insult to injury, 'blasting' caused her to gain 13 pounds,
6 and she grew so inflamed and bloated that she appeared to have gained 30 pounds.

7 18. The foregoing finally made Haavisto cease 'blasting' in July 2016, and
8 forced her to spend the next three months with drastic dietary and other lifestyle
9 changes through October of 2016. Her aggressive new health regimen caused her to
10 lose 36 pounds, and her skin hung loose off of her body, so she began 'blasting'
11 again in an attempt to firm herself back up. Without any other change to her lifestyle
12 besides the renewed 'blasting' routine, Haavisto promptly regained eight pounds.

13 19. In January of 2017, Haavisto was suffering symptoms of severe
14 hormonal fluctuation, including hair loss and loss of collagen in her face. Based on
15 Defendants' assertions that FasciaBlaster simply has no hormonal impact, and in
16 light of conversations in a Facebook discussion group (which Defendants carefully
17 monitor and control) attributing Haavisto's symptoms to 'breast implant issues', she
18 needlessly had her breast implants surgically removed on January 31. Nevertheless,
19 in March of 2017, Haavisto's hormonal symptoms were explained by a formal
20 diagnosis of Adrenal Fatigue, which her physician found totally puzzling due to
21 Haavisto's age and healthy lifestyle⁵.

22 20. Moreover, by March her cellulite had returned tenfold to her thighs.
23 'Blasting' also left unsightly 'rake marks' on her thighs and calves, and dangerous
24

25 ⁵ Haavisto's doctor expressly confessed to being confused by the patient's
26 condition, before ultimately attributing it to "toxic overload." Here, FasciaBlaster's
27 high content of Bisphenol A ("BPA") is worthy of note. See Para. 86, *infra*.
28

1 inflammation; to gauge the latter, Haavisto underwent a C-Reactive Protein ("CRP")
2 blood test. CRP level of 1 is normal. Haavisto's blood test showed her CRP level at
3 8, very dangerously high.

4 21. As of October 2017, the sustained ramifications of Haavisto's
5 'blasting' include Oxidative Stress, a severely dangerous condition affecting the
6 body's ability to remove toxins and repair cell damage which studies have connected
7 to an array of terrible ailments, including *inter alia* Parkinson's Disease, Alzheimer's
8 Disease, heart failure, chronic fatigue syndrome and depression. Haavisto also now
9 suffers Metabolic Syndrome attributable to 'blasting,' increasing her risk of heart
10 disease, stroke, and diabetes. She also continues to chronically suffer brain fog,
11 insomnia, stiff neck, and headaches.

12 22. Haavisto came forward and wrote about the foregoing dangerous and
13 scary experiences in a public FasciaBlaster discussion group on Facebook.
14 Defendants promptly removed her comments and kicked her out of the group, and
15 thereafter retaliated against her by harassing, intimidating, cyber-bullying and
16 defaming her, and on information and belief, by soliciting third parties to harass,
17 intimidate, cyber-bully and defame her, as well. The latter conduct included *inter*
18 *alia* overtly encouraging Defendants' more loyal Facebook followers to attack
19 Haavisto e.g. by leaving false negative reviews of her own businesses' Facebook
20 pages, and by targeting her with groundless accusations to the authorities, as
21 exemplified by a public Facebook post on September 7, 2017, to wit:

22 Everyone. Let's report Dari, Julie D L, Veronica Verona, Stacy Havisto [*sic*],
23 Danielle Reins, Tammy Wike, and everyone else in their hate group to the
24 FTC, FDA, FBI, the DEA, and their local Police Stations.

25 Let's look up their businesses and leave 1 star reviews.

26 Let's make sure everyone knows the truth about how hateful they are and all
of the shadiness.

27 You don't have to have been personally injured by them. If you know anyone
28 who has spent anytime [*sic*] reading their lies then you have been injured

1 (permanently). You can't get that part of your life back.

2 I'll make it easy for everyone. I'll create a copy/paste list of things they have
3 done:

4 -Harrassment [*sic*]

5 -Cyber Bullying

6 -Extortion

7 -Tortuous [*sic*] Interference

8 -Defamation

9 -Product Libel

10 -Hate Crimes

11 -Defrauding the Government (abuse of gov systems)

12 You can do it anonymously. Just crop out your face. Don't worry about
13 negative repercussions. There is nothing they can do. We need to do this in
14 order to get the truth out and take them down.

15 Come on everyone, let's do this!!!!!!

16 I will send separate e-mails to everyone with guidance from "you know who"

17 The foregoing was posted publicly by a putative Facebook user named Sarah
18 Minow, although Ms. Minow's personal Facebook page appears to be fake⁶. On
19 information and belief, Defendant Black herself created this 'shill' Facebook profile
20 in order to post the foregoing 'call to arms,' and the allusion therein to "you know
21 who" refers to Defendant Black.

22 23. All told, on information and belief Haavisto's expenses in connection
23 with using FasciaBlaster and dealing with its aftermath exceeded \$10,000.

24 \\\

25 ⁶ Ms. Minow's Facebook page displays no photos, no friends, no posts, and
26 no information of any kind, save for two telling details: (i) under the heading
27 "Groups" Ms. Minow discloses only that she is a member of "FasciaBlasters
28 Official Open Forum", and (ii) under the heading "Contact Information" the sole
entry—"http://facebook.com/sarah.minnows"—wherein Ms. Minow mysteriously
seems to have misspelled her own name.

1 **C. Loretta Oakes**

2 24. Loretta Oakes ("Oakes") is an individual who resides in Las Vegas,
3 Nevada. After conducting ample research about cellulite reduction, in or around
4 September of 2016 Oakes purchased the standard FasciaBlaster device. In or around
5 November of 2016, she purchased another version, the "Mini 2." In or around
6 February 2017, she purchased yet another version, the "Faceblaster," along with
7 multiple creams and oils marketed by Defendant for use with the devices. Oakes
8 'blasted' as directed in Defendants' marketing and instructional materials,
9 exacerbating a peripheral neuropathy condition such that she then suffered near-
10 constant tingling in her feet and sometimes too much pain to walk, including as
11 recently as within the last month. She was bedridden from November 2016 through
12 January 2017, other than for doctor appointments.

13 25. Oakes's 'blasting' caused severe bruising which has lingered as
14 hemosiderin staining on her legs for over six months since she ceased 'blasting' in
15 approximately March of 2017. Further, by disrupting the tissue connecting skin to
16 muscle, 'blasting' has turned the skin on her legs and stomach crêpey, i.e. loose and
17 wrinkled worse than her elderly mother's skin.

18 26. On information and belief, other harms attributable to 'blasting' which
19 Oakes has suffered include depression (with suicidal ideation), anxiety, nausea,
20 panic attacks, and lightheadedness, at least one incident of which caused her to lose
21 consciousness and collapse. Even after she stopped 'blasting,' Oakes's depression
22 and anxiety have persisted due to personal attacks and falsehoods leveled against her
23 on social media by Defendant Ashley Black, and by others defaming and harassing
24 Oakes at Black's behest, on information and belief.

25 27. Oakes has spent several thousands of dollars on doctor visits, pain
26 management, and a variety of expensive skin treatments in attempts to repair the
27 damage wrought by FasciaBlaster.
28

1 **C. Michelle Lanum**

2 28. Michelle Lanum (“Lanum”) is an individual who resides in Tampa,
3 Florida. Lanum is pursuing her Ph.D. in Psychology from Kaiser University, with
4 focus on the mind-body connection. When an acquaintance told her about
5 FasciaBlaster, Lanum looked into it and decided it would be a perfect subject for
6 study in connection with her degree, and she also saw an opportunity to reduce her
7 own scarring from a caesarian section several years earlier. Lanum purchased
8 multiple FasciaBlaster devices in November of 2016 and began ‘blasting’ as
9 directed.

10 29. When it came to her attention that Defendants were conducting a
11 putative “clinical trial” for the device at the Applied Science & Performance
12 Institute (“ASPI”) right in her own neighborhood, Lanum jumped at the opportunity
13 to be able to observe the study for academic purposes, and to participate for her own
14 aesthetic reasons. She participated in ASPI’s putative clinical trial of the
15 FasciaBlaster from December 10, 2016 through March 10, 2017.

16 30. Commencing with Lanum’s participation in the putative clinical trial,
17 she promptly became severely ill due to ‘blasting,’ on information and belief. Her
18 symptoms included nausea, vomiting, migraines, neck and shoulder pain, dizziness,
19 and severe gastrointestinal distress alternating between prolonged and painful
20 constipation to violent diarrhea. Lanum quickly lost 16 pounds, then three more
21 pounds. She regularly communicated these experiences to putative clinical trial
22 “researcher” Kathleen Stross, who repeatedly asserted that any notions of a
23 connection between Lanum’s symptoms and the ‘blasting’ were refuted by Lanum’s
24 regular blood testing results and other data the putative study was purportedly
25 gathering. On information and belief, the foregoing was an outright falsehood, and
26 contrary to Defendants’ repeated promises to return study participants’ medical test
27 results to them, Defendants and the putative researchers have still not done so,
28

1 ignoring multiple requests by Lanum and others.

2 31. Continued 'blasting' brought out severe varicose and spider veins on
3 Lanum's legs which had not previously been apparent, and caused an increase in the
4 appearance of cellulite. When Lanum and multiple other participants in the putative
5 clinical trial mentioned the appearance of new varicose veins, the putative
6 researchers explicitly denied that there was any connection to 'blasting,' then later
7 asserted that the varicose veins might get worse but would ultimately disappear.

8 32. More than six months after terminating her use of the FasciaBlaster,
9 Lanum's legs still exhibit varicose veins, rake marks, and crêpey skin, none of
10 which had been present before 'blasting.' Lanum continues to suffer semi-regular
11 bouts of dizziness, nausea, tinnitus, sciatica, knee problems, and nerve pain and
12 tingling radiating down through her shoulders and arms, all of which on information
13 and belief are results of nerve damage attributable to her 'blasting' over six months
14 ago. Lanum has been prescribed and is currently undergoing a course of physical
15 therapy to address her persistent nerve pain, which she and her physical therapist
16 hope will also curtail her frightening dizziness and tingling in her arms.

17 33. In Lanum's judgment based on her personal academic background and
18 experience, she found the putative researchers' behaviors to be highly erratic, their
19 methods unprofessional, and the putative clinical trial to be unscientific and
20 improper. Further, Lanum learned that Bart Jameson—one of the putative
21 researchers whom Defendants' video(s) had referred to as "Doctor Bart"—is, in
22 fact, not a doctor. When Lanum would ask procedural questions of the putative
23 researchers, e.g. for the benefit of her own research, their replies revealed shocking
24 unfamiliarity with the scientific process, generally. In one notable instance, Lanum
25 found that she had to explain to Jameson what a "hypothesis" is, and that it
26 ordinarily comes before an experiment, not after.

1 34. 'Blasting' caused Lanum to personally re-experience⁷ prior trauma,
2 which went straight to her purpose in studying the FasciaBlaster, and she braved her
3 own psychological symptoms—anxiety, restlessness, and depression—for the
4 benefit of her research. When she questioned Stross about what lengths the study's
5 Institutional Review Board ("IRB") had authorized, however, Stross provided no
6 answer, and eventually stopped responding to Lanum's voicemails, emails, and
7 Facebook messages. On information and belief, the putative clinical trial was in fact
8 never supervised by any IRB, contravening FDA regulations for any study with
9 human participants, in addition to such further administrative flaws and abuses as
10 Plaintiffs may discover in the course of litigation, at which time they may seek leave
11 to amend this Complaint to reflect same.

12 35. Defendants' putative clinical trial's physical impact on Lanum was so
13 debilitating that it forced her to drop out of a required graduate school class—Cross-
14 Cultural Methods of Tests and Measurements—which then cost her \$3,600 to
15 retake the following semester. Adding insult to injury, plus more injury, due to the
16 ASPI study's countless procedural and administrative flaws, Lanum was
17 subsequently unable to use her experience therein for the benefit of her doctoral
18 dissertation, as had been her aim all along. This wasted time and effort will now
19 require her to extend the time for her dissertation research, at the cost of an
20 additional \$6,600 in tuition for the extra semester. Finally, treatment measures to
21 repair the damage wrought by Lanum's FasciaBlaster experience have cost over
22 \$600 to date, on information and belief, and she expects that she may ultimately
23 require costly plastic surgery if her currently ongoing treatments ultimately prove
24

25 ⁷ 'Re-experience' is the clinical terminology associated with the phenomenon
26 whereby e.g. Post Traumatic Stress Disorder ("PTSD") patients feel their previous
27 trauma all over again, as though it were happening in the present.
28

1 ineffective.

2 **D. Julia Lefebvre**

3 36. Julia Lefebvre (“Lefebvre”) is an individual who resides in Hiram,
4 Maine. Lefebvre is an independent contractor performing background checks and
5 employee and renter screenings. Lefebvre and her husband booked a cruise for
6 November 2016 in order to renew their marriage vows, in preparation for which
7 Lefebvre researched “cellulite reduction” on the Internet in order to look her best in
8 bathing suit or short skirt for her romantic vacation. Her research caused Facebook’s
9 advertising algorithm to begin targeting her with FasciaBlaster ads, which then led
10 her to the FasciaBlaster website, Defendants’ promotional videos, and public
11 Internet forums populated by 90,000+ putative satisfied customers, wherein
12 Lefebvre noted a lack of any negative feedback whatsoever. She purchased
13 FasciaBlaster in September 2016 and promptly began ‘blasting’ five times per week.

14 37. Though Lefebvre had purchased FasciaBlaster only to reduce cellulite
15 on her thighs, Defendants’ marketing promises led her to also ‘blast’ her face, neck,
16 arms, stomach, back and buttocks regularly. Before long her thighs, stomach, back
17 and arms began to show severe bruising, but she carried on ‘blasting’ based on
18 Defendants’ admonition that results would be “worse before better!” Lefebvre
19 followed Defendants’ instructions and encouragement to the effect that her
20 ‘blasting’ build up to a pain level of “seven out of 10,” that she “blast down to the
21 bone,” and that “violent blasting does a body good.” Lefebvre ceased blasting in the
22 last week of October 2016, in order that her accumulated bruises would have time to
23 fade away before her cruise, but the bruises simply changed color and remained as
24 ugly hemosiderin stains all over her ‘blast’ areas. To make matters worse, the
25 appearance of cellulite on her thighs had significantly worsened. The discoloration
26 and cellulite made her too self-conscious to wear shorts, bikini, or a short skirt, thus
27 ruining what was supposed to be a romantic vacation.
28

1 38. Notwithstanding the foregoing, on the basis of Defendants' "worse
2 before better" mantra, Lefebvre continued 'blasting' five times per week hoping for
3 improvement before another cruise, this one for her whole family, scheduled for
4 January 2017. Then on December 23, 2016, while driving home from a shopping
5 trip to the mall, Lefebvre was overcome with severe dizziness, her field of vision
6 narrowed, and her hearing muffled; it felt like a heart attack, or severe panic attack⁸,
7 the likes of which she had never experienced before. She quickly pulled off the road
8 and phoned her children, who had to come get her. A few days later, she had the
9 same experience again, this time in the middle of 'blasting.' On January 23, 2017,
10 Lefebvre saw stars and collapsed to the floor while 'blasting,' and lay on the floor
11 unable to speak or move for three to five terrifying minutes, her body twitching and
12 convulsing involuntarily. When her husband came home, he took her to the
13 emergency room, where a physician told her that she may have triggered the episode
14 by overheating and overstimulating her vagus nerve, i.e. Vasovagal Syncope, which
15 clearly would have been a consequence of 'blasting.' Lefebvre subsequently
16 continued blasting, but did so more gently and with less heat applied to her abdomen
17 in order to avoid a response from her vagus nerve.

18 39. Lefebvre continued to suffer debilitating panic attacks multiple times
19 per week until shortly after she ceased 'blasting' in May 2017. Her last such attack
20 was in June, but she felt compelled to refrain from driving her car between January
21 and August of 2017, other than a handful of short trips alone to the market, for fear
22 of an accident. These attacks understandably affected her ability to work and engage
23 with her family and others, constituting a severe impact on her quality of life

24
25 ⁸ On information and belief, this and subsequent similar episodes were not
26 panic attacks, but Vasovagal Syncope, however the Complaint refers to them as
27 panic attacks for clarity's sake to convey the abruptly incapacitating pain, anxiety,
28 weakness, and loss of physical control.

1 generally.

2 40. Beginning in January 2017, Lefebvre noticed newly rapid aging in her
3 face, including dramatic deepening of the so-called 'marionette lines.' Since then
4 she has spent over \$4,000 on collagen treatments and supplements, laser therapy,
5 microcurrent, microneedling, and other reparative measures to try to get her face
6 back to its pre-'blasted' state. Furthermore, over three months after she ceased
7 'blasting,' Lefebvre's legs still have hemosiderin stains, unsightly rake marks, and
8 worse cellulite than they exhibited a year ago.

9 41. Lefebvre has been subject to defamation, harassment, intimidation and
10 cyber-bullying after she honestly relayed her experiences in e.g. the "Master
11 Blaster" group on Facebook, including *inter alia* being mentioned in a Facebook
12 group post on September 7, 2017 which explicitly sought to incite group members to
13 *inter alia* attack Lefebvre's business with false negative online reviews. On
14 information and belief, the putative Facebook user "Sarah Minow" who posted said
15 incitement was in fact a fake 'shell' profile created and wielded by Defendant Black,
16 herself, or at her behest. Likewise, putative Facebook user "Georgia Peach" falsely
17 asserted that Lefebvre has committed fraud. On information and belief, "Georgia
18 Peach" is also a shell profile created and wielded by Defendant Black.

19 **E. Sue Grlicky**

20 42. Sue Grlicky ("Grlicky") is an individual who resides in Brooklyn,
21 Ohio. A 52 year-old office manager for a chemical company, Grlicky was in good
22 health overall, but in the Spring of 2017 she was suffering from lower back pain in
23 her psoas muscle. She undertook research on the subject via Google, which on
24 information and belief prompted Facebook to target her with an ad for
25 FasciaBlaster. Grlicky then assiduously researched FasciaBlaster over the course of
26 four weeks—she joined the "Ashley Black Guru" Facebook discussion group,
27 reviewed over a hundred product reviews therein, watched numerous promotional
28

1 and instructional videos, and purchased and read Defendant Black's book, The
2 Cellulite Myth: It's Not Fat, It's Fascia, cover to cover—before purchasing the
3 device and accessories in April of 2017. She commenced using it immediately,
4 targeting her lower back, shoulders, neck, scalp, abdomen, buttocks, and legs (inner,
5 outer, front, and back), for approximately one minute per target area, approximately
6 five times per week after a hot bath.

7 43. Within her first week of 'blasting' Grlicky began to experience severe
8 nausea, headaches, body aches, fatigue, and depression. She wrote to Black about
9 her symptoms via Facebook, to which the latter responded that "detox can really be
10 rough ... [it's] no fun but it's a necessary, TEMPORARY evil that is needed to
11 release all the gunk that's keeping your body from functioning at 100%." Grlicky
12 then took a break from 'blasting' for 2-3 days, then resumed 'blasting' as before, but
13 more gently and for shorter duration, and her symptoms improved slightly in
14 severity by the end of her second week, but did not go away.

15 44. During her third week of 'blasting,' Grlicky stumbled upon another
16 Facebook discussion group, this one dedicated to FasciaBlaster's adverse effects,
17 which caused her to draw the connection that her persistent illness was more than
18 the mere beneficial 'detoxification' that Black had asserted it was, so Grlicky then
19 ceased 'blasting.' Shortly thereafter, she experienced the abrupt onset of a stabbing,
20 throbbing, burning neck and shoulder pain. This new symptom was severe, constant,
21 and scary. Over the following few weeks Grlicky sought treatment from a
22 chiropractor and four different massage therapists—one of whom told her that her
23 neck and shoulder area was "highly inflamed"—until one day a tingling began to
24 radiate down her right arm. Her chiropractor diagnosed her with a pinched nerve,
25 and attempted a special chiropractic adjustment for that diagnosis, but it
26 accomplished nothing. Desperate and afraid, Grlicky went to the Cleveland Clinic in
27 early July, where she was referred to a neurologist who confirmed the pinched nerve
28

1 diagnosis. Grlicky underwent MRIs and x-rays, and the neurologist prescribed
2 neuropathic medication Gabapentin and pain medication Tramadol. This course of
3 treatment improved Grlicky's pain but did not fix it, and treatment efforts are
4 ongoing.

5 45. While at work on July 17, Grlicky felt a sudden mild pain in her hip,
6 which within 15 minutes became excruciating, whereupon she could not walk or
7 stand. A call to 911 brought an ambulance to take Grlicky to the Cleveland Clinic
8 Emergency Room, where she was subjected to CT scans, more x-rays, blood tests,
9 etc. ER personnel asked her "were you in some kind of accident?" "No," she
10 replied, "why?" She was then told that a burst blood vessel had caused a massive
11 hematoma and internal bleeding in her pelvic region (left side). After trying and
12 failing to find any exterior bruising in the area, the ER doctor told Grlicky that "this
13 is highly unusual, not something we see often [other than after e.g. a violent
14 collision]." Grlicky was admitted to the hospital for an overnight stay in order for
15 doctors to stop her internal bleeding.

16 46. Since the foregoing hospital stay, Grlicky has had appointments with
17 her primary doctor, a hematologist, physical and massage therapists, and a holistic
18 practitioner. Nonetheless, Grlicky still experiences occasional pain on the left side
19 of her pelvis, causing her to suffer extreme anxiety to ever be alone, lest her blood
20 vessel burst again, or worse. Her primary doctor concluded that this entire episode
21 was attributable to Grlicky's 'blasting,' and explicitly stated "you easily could have
22 died from internal bleeding. You should sue those people [Defendants]." Grlicky
23 also now suffers great anxiety about the possibility of losing her job, having had to
24 take off work to some degree roughly every week since her pinched nerve for
25 medical or therapeutic appointments, or on occasions when her pain is unbearable.

26 47. All of Grlicky's medical treatment described herein—including trips to
27 the Cleveland Clinic, ER, ambulance, chiropractor, physical and massage therapists,
28

1 and holistic practitioner—came at a combined cost in excess of \$23,800.08, of
2 which Grlicky has paid \$6,756.95 out of pocket, to date.

3 **F. Tilly Dorenkamp**

4 48. Tilly Dorenkamp (“Dorenkamp”) is an individual who resides in
5 Pinellas Park, Florida. Dorenkamp is an artist with average yearly income from
6 commissions of \$20,000 – \$25,000 per year. She enjoyed excellent muscle tone due
7 to attending Pilates classes roughly five times per week for several years. On the
8 recommendation of a friend, Dorenkamp purchased FasciaBlaster in October 2016
9 hoping to relieve pain from fibromyalgia and arthritis, and carefully adhered to the
10 instructions provided in Defendants’ YouTube videos.

11 49. Dorenkamp then learned about and opted to take part in ASPI’s
12 putative clinical trial from December 2016 through March 2017. Per the study
13 protocols, five times per week she used a portable sauna device for 20 minutes, then
14 ‘blasted’ for five minutes per target area: her abdomen, and then the front, back,
15 inside, and outside of each leg (i.e. 20 minutes per leg in total). A month into the
16 study she was given a FaceBlaster, and began ‘blasting’ her face and neck to reduce
17 the effects of aging. As the putative clinical trial progressed, Dorenkamp
18 complained numerous times that ‘blasting’: caused severe nerve pain in her legs and
19 knees; worsened the Restless Leg Syndrome (“RLS”) from which she suffered at
20 night; and left her utterly exhausted and bedridden such that she could not perform
21 any other physical activity on ‘blasting’ days. In the last few weeks of the putative
22 clinical trial, Dorenkamp’s suffering was so severe that her Rheumatologist
23 suggested she drop out.

24 50. During the putative clinical trial, an anxiety condition which
25 Dorenkamp had previously managed for 20 years—with anti-anxiety medication
26 Clonazepam (.5 mg)—suddenly worsened, and developed into deep depression,
27 causing her primary care physician to double her Clonazepam dosage and prescribe
28

1 an extra half-dose of an additional anti-anxiety medication, Zoloft. Dorenkamp
2 failed to draw a connection between her depression and the putative clinical trial
3 until May of 2017. To date, her exacerbated anxiety condition gives her stress
4 headaches almost every time she leaves the house, which was not the case before
5 her FasciaBlaster experience. She was prescribed yet another anti-anxiety
6 medication, Buspirone (15mg), in early September of 2017.

7 51. After the putative clinical trial ended, Dorenkamp tried 'blasting' three
8 more times. The third time, on May 9, 2017, abruptly brought on a severe
9 thunderclap headache, and elevated her resting heart rate to 185 beats per minute
10 ("BPM") (from her average resting heart rate of approximately 67 BPM),
11 necessitating an emergency room visit. Before this ER visit, Dorenkamp had
12 managed a Tachycardia condition for 20 years with 50mg prescription of Atenolol.
13 Following this ER visit, her cardiologist doubled her Atenolol dosage due to
14 severely worsened heart palpitations, elevated pulse, and mitral valve prolapse
15 diagnoses. The cardiologist also prescribed a nuclear stress test which Dorenkamp
16 has yet to undergo because the entire \$1,000 cost will have to come out of pocket.

17 52. Beyond her cardiological difficulties, 'blasting' severely increased
18 what had previously been quite minimal cellulite on Dorenkamp's legs; the skin now
19 sags off of her legs, there is a conspicuous dent in her thigh, and her calf muscle
20 atrophied to the point that she cannot see it and can barely feel it. 'Blasting' her face
21 and neck has also caused severely sagging skin, dramatically accelerating the
22 appearance of aging, notwithstanding that she was assiduously faithful to ASPI
23 researchers' and YouTube video instructions at all times.

24 53. Before she began 'blasting,' on an average day Dorenkamp
25 experienced a pain level of 3-4 (out of 10) from her fibromyalgia and arthritis
26 conditions. Since May of 2017, on an average day her pain level is 5-7 out of 10,
27 notwithstanding her efforts to manage the pain with ibuprofen and powerful
28

1 painkiller Tramadol (200mg). Her RLS condition has also worsened considerably,
2 disrupting her sleep cycles more than it ever had before. Dorenkamp has not been
3 able to work on her art since December 2016, and as a result she has multiple
4 commissions outstanding, harming her professional reputation.

5 54. Dorenkamp has been subject to defamation, harassment, intimidation,
6 and cyber-bullying, constituting intentional infliction of emotional distress by
7 Defendants, and others on their behalf, in retaliation for her having honestly relayed
8 her experiences in e.g. the “Ashley Black Guru” group discussion page on
9 Facebook. Dorenkamp was also the victim of malicious prosecution in the form of a
10 frivolous lawsuit against her by Defendants, which has been dismissed. Recently, at
11 Defendants’ behest and direction on information and belief, individuals⁹ supporting
12 Defendants have sought to harass, embarrass, and intimidate Dorenkamp on
13 Facebook by the unauthorized public posting of unflattering photos of her, and
14 health-related records which, on information and belief, Defendants permitted to be
15 publicized in violation of numerous statutes and regulations, e.g. HIPAA.

16 55. On information and belief, Dorenkamp’s FasciaBlaster use will have
17 necessitated medical and therapeutic treatments costing her more than \$15,000.

18 **G. Dina Salas**

19 56. Dina Salas (“Salas”) is an individual residing in Las Vegas, Nevada.
20 Salas is 40 years old, has Multiple Sclerosis (“MS”), and in spite of a vegan diet and
21 taking yoga classes three times per week, she was frustrated and embarrassed by
22 cellulite on her thighs, knees and calves. In June of 2016, her cousin told her about
23 FasciaBlaster. Salas purchased one, but did not begin using it until October or
24

25 ⁹ The individuals in question undertook the described cyber-bullying for
26 Defendants’ benefit *if*, that is, they are not in fact merely fake Facebook personae
27 operated by Defendants themselves, as alleged herein. See e.g. Para. 94, *infra*.
28

1 November of 2016, and only approximately twice a week, and gently, because it
2 was so painful. Salas saw no beneficial results, only dramatic bruising, and stopped
3 'blasting' in or around December 2016.

4 57. Notwithstanding that she had already stopped 'blasting,' Salas
5 remained a member of the Defendants' "FasciaBlasters" Facebook group, and in
6 early 2017 on the basis of new success stories and compelling 'before and after'
7 photos still cropping up in her Facebook News Feed, she decided to give 'blasting'
8 another try. This time her regimen entailed 'blasting' roughly every other day, and
9 much more strenuously, as she was encouraged by Defendants and others¹⁰ in the
10 discussion group to do so at a pain level of 7 out of 10. Salas saw no positive results,
11 only renewed, dark bruising.

12 58. A few weeks after reinitiating her 'blasting,' as Salas's enthusiasm
13 began to wane yet again, in her Facebook News Feed she saw a video posted by
14 Defendant Black with a caption¹¹ asserting that FasciaBlaster is effective at treating
15 Parkinson's disease and MS—both neurodegenerative conditions—by "lessen[ing]
16 lesions," i.e. the scars on the brain and spinal cord which cause MS. Further research
17 on Google then led Salas to a posting by Defendant(s) on social media

18
19 ¹⁰ Notably, shortly after Salas had renewed her attention to the Facebook
20 group, she received multiple Facebook friend requests from previously unknown
21 individuals, who were then enthusiastic FasciaBlaster cheerleaders, pushing and
22 prodding Salas to keep up the aggressive 'blasting' every time she expressed any
23 doubts. On information and belief, these individuals were either fake Facebook
24 profiles operated by Defendants, or paid motivators operating at Defendants' behest;
at one point in or around May 2017, Salas pointedly asked one of them if she were a
paid "motivator," and the other profile immediately 'unfriended' Salas.

25 ¹¹ Salas saw this video and its caption before she was summarily kicked out of
26 Defendants' "FasciaBlasters" Facebook group in June of 2017. On information and
27 belief, this claim pertaining to MS may have been removed since then, however not
28 before Salas and others similarly situated relied on it.

1 website/application Instagram, claiming that FasciaBlaster is “really helping with
2 MS patients – not only with symptoms but the lesions are lessening on the MRIs ...
3 I've known for years ... that fascia work helps with MS.” After stumbling upon the
4 foregoing social media posts, and then noticing more and more (putative¹²)
5 participants in the Facebook group who claimed to be treating MS with
6 FasciaBlaster, Salas’s enthusiasm understandably skyrocketed, and she added her
7 abdomen and back to her ‘blasting’ routine.

8 59. Approximately a month into her renewed ‘blasting’ routine, Salas
9 began suffering an extraordinarily severe itchiness. It was so uniquely awful that it
10 sent her to the emergency room and subsequently to a neurologist, who diagnosed
11 her condition as chronic Pruritis. Far from a garden-variety scratchable itch, Salas
12 experienced deep, torturously unyielding irritation everywhere throughout her body,
13 literally from her toes to scalp, and particularly bad in her tongue and eyeballs. The
14 maddening nerve pain deprived Salas of sleep and otherwise disrupted every aspect
15 of her life.

16 60. At the beginning of May, tortured by Pruritis, Salas quit ‘blasting’ for
17 good. Months of ‘blasting’ did not cure Salas’s MS, nor improve it to even the
18 slightest degree as Defendants claimed it would. All of that ‘blasting’ did, however,
19 significantly worsen her cellulite, and decorated her legs with a brand new network
20 of unsightly spider veins, where she had previously had none. For the first time in
21 decades, Salas experienced severe and painful oral Herpes outbreaks *repeatedly*
22 since first using the FasciaBlaster. She also gained 20 pounds since first ‘blasting,’
23 attributable thereto on information and belief because she had made no other change
24

25 ¹² On information and belief, some if not all of these individuals whom Salas
26 saw extolling the virtues of ‘blasting’ for MS treatment were/are fake Facebook
27 profiles or paid motivators. See e.g. Para. 94, *infra*.
28

1 to her vegan, yoga-enthusiast lifestyle.

2 61. Along with the total failure to improve her MS in the slightest, her
3 abrupt weight gain, brand new spider veins, resurgent Herpes outbreaks, and
4 torturous unscratchable itching from head to toe, on information and belief Salas's
5 'blasting' disrupted her hormonal levels, all of which combined to throw her into
6 severe depression.

7 62. To date, the various medical treatments necessitated by Salas's
8 FasciaBlaster experiences add up to approximately \$4,000 out of her pocket and
9 several thousand more paid on her behalf in financial assistance, on information and
10 belief. This figure of course fails to account for e.g. the future cosmetic treatments
11 required to fully repair all the damage wrought by Defendants' products and
12 business practices.

13 **H. Arlene Rodriguez**

14 63. Arlene Rodriguez ("Rodriguez") is an individual residing in Hanford,
15 California. She is a 38 year-old waitress. After seeing Defendants' advertising in her
16 Facebook News Feed, she joined the Facebook "FasciaBlasters" discussion group to
17 research the product. Seeing no meaningfully negative reviews, and eager to get rid
18 of cellulite on her thighs, she purchased the device in mid-November 2016 and in
19 late November commenced 'blasting' her thighs, abdomen, and arms, for roughly
20 five minutes in total, roughly three times per week in a very hot bath or shower.

21 64. Right away, Rodriguez would experience nausea, dizziness and
22 lightheadedness almost every time after 'blasting,' and frequently headaches.
23 Beginning in mid-December, Rodriguez began experiencing burning body aches as
24 well, which were sufficiently worrisome that she went to a doctor to be tested for
25 Lupus, arthritis, etc., but the tests were negative. She combed the Facebook
26 discussion group for feedback similar to her experiences from other users, and
27 finding none, Rodriguez carried on 'blasting.' Even as the cellulite which motivated
28

1 her purchase was worsening substantially, Rodriguez continued 'blasting' in
2 reliance on Defendant Black's representations that increased appearance of cellulite
3 is a temporary result of FasciaBlaster's breaking up the fascia in "layers," and
4 Defendants' famous, persistent refrain: "worse before better!"

5 65. In mid- December, Rodriguez began experiencing unusual mood
6 swings and increased anxiety, but failed to draw any connection to her 'blasting.' In
7 or around February 2017 Rodriguez bought a second FasciaBlaster, the 'Mini 2'
8 model, and extended her 'blasting' sessions to an average of seven minutes on the
9 basis of enthusiastic encouragement and authoritative advice and promises made by
10 Defendants (and other Facebook profiles which, on information and belief, were
11 either fake, or paid motivators) in Defendants' Facebook discussion group. In or
12 around March 2017, seeing her doctor about her unexplained persistent mood
13 swings and increased anxiety, she was prescribed Zoloft (15mg).

14 66. In or around May of 2017, Rodriguez's body aches grew so severe that
15 at one point she was bedridden for two days, yet she persisted in 'blasting.' Not long
16 thereafter, she happened upon a report about FasciaBlaster on the Facebook page of
17 Goop, a trendy lifestyle company. Among the public's comments on the Goop
18 posting was a link to a Facebook group for dissatisfied FasciaBlaster users,
19 providing Rodriguez's first inkling that the device might be remotely fallible; the
20 user comments in this second Facebook group constituted the first meaningfully
21 negative reviews about FasciaBlaster which Rodriguez had seen, after roughly six
22 months of participating in Defendants' own carefully monitored, controlled, 100%
23 enthusiastically positive discussion group. Rodriguez promptly stopped blasting at
24 this point, and began to make more pointed and less positive inquiries in the
25 Defendants' Facebook discussion group. She was then promptly kicked out of that
26 group, and blocked from the "Ashley Black Guru" Facebook page wherein she
27 might otherwise have been able to comment about her experiences e.g. for the
28

1 benefit of third parties.

2 67. Between a week and 10 days after Rodriguez ceased 'blasting,' she
3 developed the beginnings of a strange rash on her lower back. After another week it
4 had begun to spread, and it itched severely. Her doctor initially diagnosed the rash
5 as an allergic reaction, and prescribed Loratidine (10mg). Another week or two
6 later, the rash had spread like wildfire, all over Rodriguez's thighs, back, sides,
7 breasts, upper chest, and down her right arm. She returned to the doctor, who
8 inquired whether Rodriguez had traveled recently, or eaten anything exotic, or
9 undertaken any other new experience or meaningful lifestyle change of any kind.
10 The answer was no, and Rodriguez mentioned FasciaBlaster. Her doctor had never
11 heard of it, so Rodriguez explained Defendants' 'blasting' theories, to which the
12 doctor expressly replied that there was "a strong possibility" that FasciaBlaster had
13 caused the rash, and prescribed a 10-day course of steroid Prednazone (5mg).

14 68. Rodriguez took her prescribed Prednazone for 10 days, during which
15 the rash improved. Three days after the tenth day, however, the rash returned
16 aggressively, even worse and more painful than it had been previously, and
17 extremely unsightly (the factfinder will undoubtedly find photos thereof to be highly
18 upsetting). Rodriguez went back to the doctor again, had tissue samples taken for
19 biopsy, and was given a prescription for anti-fungal medication Terbinafine
20 (250mg) which she only took for a short time before receiving her biopsy results
21 back with her diagnosis: chronic superficial perivascular dermatitis, i.e.
22 inflammation of her blood vessels. In response, her doctor doubled the previous
23 Prednazone prescription dosage (to 10mg) and tripled its duration (30 days), added
24 prescriptions for Ranitidine (150mg) and Triamcinolone (1%) steroid cream to the
25 menu, and advised Rodriguez to supplement all of the foregoing with Benadryl any
26 time the itch grew too unbearable. All of the foregoing finally began to put the rash
27 on the retreat, and at the end of 30 days, the doctor prescribed another 30 days of
28

1 half the previous Prednazone dosage (back down to 5mg), then another 30 days of
2 the next lowest available dosage (1mg) in order to wean Rodriguez off of it; the rash
3 is much improved as of the date hereof but, notably, it is not gone.

4 69. During the Summer of 2017, temperatures in California's Central
5 Valley routinely exceeded 100 degrees. At that time, at the height of Rodriguez's
6 extremely unsightly rash, she was obliged to wear long sleeved shirts and long pants
7 to cover it, rather than the tank tops and shorts or skirts most women would prefer to
8 wear on hundred-degree days. Obviously such clothes were highly uncomfortable,
9 and the predictably profuse sweating that resulted ramped up Rodriguez's already
10 itchy discomfort into a painful burning sensation. On two occasions, between June
11 and July, she was sent home early from her waitressing job because constantly-
12 scratching waitresses are not good for business. She lost wages and tips totaling
13 \$300 or more as a result.

14 70. As of the date hereof, almost 11 months since she first 'blasted,'
15 Rodriguez's cellulite remains worse than it was before, and has spread from her
16 thighs to her buttocks, where it had not appeared previously. Her inner thighs bear
17 distinct, unsightly rake-marks (matching the dimensions of the FasciaBlaster claws),
18 notwithstanding that roughly five months have passed since she last raked them.
19 Rodriguez had minor spider veins on her outer knees before she purchased
20 FasciaBlaster. As of the date hereof, those spider veins are significantly darker,
21 thicker, wider, and more unsightly than they were, and they have been joined by
22 brand new networks of unsightly spider veins above her knees, prominently on the
23 front of her thighs.

24 **I. Jerry Gaines**

25 71. Jerry Gaines ("Gaines") is an individual residing in Tampa, Florida. He
26 is the grandfather of Plaintiff Lanum. When the latter purchased multiple
27 FasciaBlaster devices in November of 2016 (see Para. 28, *supra*), she gave one to
28

1 Gaines and told him to only use the device on his head and neck—pursuant to the
2 “migraine relief protocol” specified by Defendants’ on their FasciaBlaster Facebook
3 page, and to emulate Defendants’ online videos, photos and testimonials of subjects
4 from a putative hair growth study—and on his abdomen as recommended by
5 Defendant Black in other marketing and instructional materials. Gaines ‘blasted’
6 two to three times per week, for twenty minutes at a time in the shower or sauna,
7 beginning in late November 2016, right up until he suffered a stroke in June 2017.
8 Gaines suffered damage to cranial nerve no. 7, adversely affecting his speech and
9 causing severe expressive aphasia. CT scan results revealed “loss of grey-white
10 differentiation and cortical effacement in the left frontal cortex, in the left MCA
11 [(middle cerebral artery)] distribution.” Another scan revealed “left M2 [a segment
12 of the MCA] with diminished flow.” A third test, cerebral angiography, showed
13 “distal M2 occlusion.” A fourth test, brain MRI, showed “acute left MCA territory
14 infarct in the left frontal lobe + a few areas of punctate restricted to fusion in the
15 right frontal and parietal lobes.”

16 72. Following Gaines’s stroke, Lanum found testimonials from dissatisfied
17 FasciaBlaster users online, which made reference to the device’s dangerous
18 tendency to release blood clots. Lanum brought the foregoing to the attention of
19 Gaines and his physician, and the latter demanded that Gaines immediately cease all
20 ‘blasting’; specifically, his doctor expressly said “throw that thing [FasciaBlaster]
21 away!” Since then, Gaines has had to undergo extensive speech therapy and
22 cognitive exercise programs, as well as physical therapy and treatments to restore
23 his neurological system, including multiple weeks at an expensive in-patient
24 rehabilitation facility.

25 **Class Action Allegations**

26 73. Plaintiffs bring this action on their own behalf and as a Class Action
27 under the provisions of e.g. Cal. Civ. Code § 1781, on behalf of all members of a
28

1 plaintiff Class defined as: all persons who have purchased and/or used
2 FasciaBlaster, or who will have done so at some point prior to resolution of the
3 Plaintiffs' claims herein.

4 74. Plaintiffs do not know the exact number of claimed Class members, but
5 on information and belief, they number in the tens of thousands if not more. Due to
6 the nature of the trade and commerce involved, the claimed Class members are
7 sufficiently numerous and geographically dispersed throughout the U.S. so that the
8 joinder of all claimed Class members is impracticable.

9 75. There is considerable commonality here among the claimed Class
10 members in that each has purchased or used, or will have purchased or used, a
11 dangerous FasciaBlaster device(s) prior to e.g. the implementation of any injunctive
12 relief ordered as a result of this lawsuit. The various harms FasciaBlaster has
13 wrought on each Plaintiff constitute further commonality between each Plaintiff and
14 all claimed Class members who have suffered, or will suffer before this matter is
15 resolved, the same or substantially similar¹³ type(s) of physical and commercial
16 injuries as any given Plaintiff(s); hopefully, many claimed Class members have been
17 fortunate enough to avoid serious injury, but any individual who nevertheless has
18 failed or will fail to achieve the 'blasting' results promised by Defendants finds
19 commonality with the Plaintiffs regarding e.g. causes of action for false advertising,
20 breaches of express and implied warranty, and fraud, if not also others.

21
22 ¹³ For example, Plaintiff Elson alleges that the Epstein-Barr virus which
23 previously lay harmlessly dormant in her system was released and reawakened by
24 'blasting,' making Elson extremely ill. (See Para. 13, *supra*.) There is thus
25 commonality between Elson and any putative Class member who also became ill
26 after having a previously dormant virus reactivated by FasciaBlaster use; the
27 possibility that the Class member's specific virus might differ (e.g. Shingles) does
28 not inherently defeat the commonality of the cause, nor the consequences, of its
revival from prior dormancy.

1 76. Plaintiffs and claimed Class members have a common interest in
2 determining the following:

- 3 (a) whether Defendants engaged in false or misleading advertising;
4 (b) whether FasciaBlaster caused the injuries suffered by users
5 thereof;
6 (c) whether acts and omissions by Defendants contributed to the
7 injuries suffered by FasciaBlaster users;
8 (d) whether acts and omissions by Defendants were negligent,
9 grossly negligent, reckless, fraudulent, or any combination thereof; and
10 (e) that Plaintiffs and other members of the claimed Classes have
11 been, or are substantially likely to be, damaged by Defendants'
12 wrongful acts and/or omissions.

13 77. Plaintiffs' claims are typical of the claims of all Class members.
14 Plaintiffs will fairly and adequately protect the interests of the Classes. Plaintiffs are
15 typical users of FasciaBlaster devices and accessories sold throughout the United
16 States. Their interests are coincident with, and not antagonistic to, those of the other
17 members of the Class. In addition, Plaintiffs are represented by counsel who are
18 competent and experienced in the prosecution of class action litigation.

19 78. The prosecution of separate actions by individual members of the
20 plaintiff Class would create a risk of inconsistent or varying adjudications,
21 potentially establishing incompatible standards of conduct for Defendants and
22 inconsistent remedies available to injured Class members nationwide.

23 79. The questions of law and fact common to the members of the
24 Subclasses predominate over any questions affecting only individual members,
25 including legal and factual issues relating to liability for actual, general, and punitive
26 damages, and appropriateness of injunctive relief.

27 80. A class action is superior to other methods for the fair and efficient
28

1 adjudication of this controversy. Treatment as a class action will permit large
2 numbers of similarly situated persons to adjudicate their common claims in a single
3 forum simultaneously, efficiently, and without the duplication of effort and expense
4 that numerous individual actions would engender. Class treatment will also permit
5 the adjudication of claims by many Class members who could not afford
6 individually to litigate the numerous claims such as are asserted in this Complaint.
7 The plaintiff Class is readily ascertainable. Finally, this class action is not likely to
8 present such difficulties in management that would preclude its maintenance as a
9 class action.

10 **IV. FACTS COMMON TO ALL CAUSES OF ACTION**

11 **FasciaBlaster Marketing**

12 81. Defendants do or did advertise FasciaBlaster through multiple media
13 avenues, including *inter alia*: website www.fasciablaster.com; website
14 www.AshleyBlackGuru.com; Defendant Black's book The Cellulite Myth: It's Not
15 Fat, It's Fascia; pervasive targeted¹⁴ advertising, putatively instructional videos, and
16 putatively open discussion forums on social media websites/applications including
17 *inter alia* Facebook, Instagram, and YouTube; and by promotional interviews and
18 other varieties of marketing tie-ins e.g. on the Today Show and EXTRA television
19 programs, in Essence and Shape magazines, and on the much-ballyhooed lifestyle
20 website GOOP.com.

21 82. Putatively instructional materials (e.g. over 100 videos) and discussion-
22 oriented forums (e.g. multiple Facebook discussion groups) created and/or

23
24 ¹⁴ On information and belief, Defendants enjoy Facebook's top-of-the-line
25 targeted advertising package, whereby Facebook's algorithm communicates with a
26 user's web browser program to learn that e.g. she had previously run a Google
27 search for "cellulite," causing Facebook to automatically place Defendants' ad
28 prominently near the top of the user's Facebook 'News Feed' the next time she
scrolls through it.

1 moderated by Defendants feature public representations asserting or purporting to
2 reinforce assertions about the effectiveness of Defendants' products and techniques
3 for their advertised purposes. Moreover, on information and belief Defendants did
4 and do create and operate shell (i.e. fake) Facebook profiles, and/or surreptitiously
5 contract with third party 'motivators,' in order to give the false public impression
6 that these are disinterested parties as they broadcast glowing third-party feedback
7 and/or oppose, attack, and seek to undermine any negative third-party feedback.
8 Finally, representations on product packaging also qualify as marketing.

9 83. All putatively 'informational' material disseminated by Defendants
10 regarding FasciaBlaster, in any medium, has the underlying intent and effect of
11 advertising FasciaBlaster products, accessories and techniques. On information and
12 belief, most if not all of the foregoing relies on false and/or deceptive claims
13 pertaining to health benefits, aesthetic benefits, and the putatively scientific bases
14 for such claims, including but not limited to false representations of the
15 medical/academic qualifications of individuals and regulatory agency support for
16 the outcomes promised by the Defendants.

17 84. The following is a nonexhaustive list of Defendants' false and/or
18 misleading representations about FasciaBlaster's health benefits, aesthetic benefits,
19 the medical/academic qualifications of Defendants' agents and employees, the
20 scientific legitimacy of Defendants' putative clinical trial, and regulatory agency
21 support for Defendants' commercial promises, *inter alia*:

22 (a) Defendants have stated that FasciaBlaster is "FDA Approved."

23 °In fact, FasciaBlaster is merely registered with the FDA, as a Class 1
24 medical device ("massager"). Class 1 devices are considered low-risk
25 and subject to the lowest degree of regulatory control. For example,
26 dental floss is classified as a Class 1 device. FasciaBlaster is not FDA
27 *approved* for the myriad medical uses promoted by Defendants.
28

1 (b) Defendants claimed as far back as September 2016, if not earlier,
2 that their products were subject to “clinical study” and “double-blind
3 scientific research.” °In fact, on information and belief the only
4 putatively scientific research was the putative clinical trial undertaken
5 at ASPI from mid-December 2016 through mid-March 2017.

6 Moreover, as noted *supra* by participant Plaintiffs, the study was
7 dubiously scientific, was conducted without IRB oversight, violated
8 HIPAA and FDA protocols, and was certainly not “double-blind”
9 because there was no control group versus test group, but rather simply
10 35 participants all doing the same ‘blasting’ and submitting their
11 results. Contrary to innumerable prior representations by Defendant
12 Black and others, an officer of Defendant ADBI recently admitted that
13 there has been no genuine “clinical” study.

14 (c) Defendants have claimed and/or intentionally implied, *inter alia*:
15 that Defendant Black is a Licensed Massage Therapist, scientist, and
16 “Inventor of the Year” nominee; that former spokesperson Dari Samia
17 is a medical doctor; that spokesperson and putative researcher Bart
18 Jameson is a doctor; and that spokesperson and putative researcher
19 Kathleen Stross is a neuroscientist. °In fact, on information and belief,
20 none of these people possess the referenced qualifications.

21 (d) Defendants have claimed that FasciaBlaster is 100% safe; on
22 May 18, 2017, Defendant Black stated in a promotional video that no
23 woman had reported injuries to her; as recently as August 31, 2017,
24 Black stated “[t]here are no serious injuries reports (*sic*) ... [w]e
25 investigate all claims.” °In fact, on information and belief, thousands of
26 FasciaBlaster users have experienced adverse effects from ‘blasting.’
27 According to an FDA Inspection Report, a minimum of 70 such users
28

1 reported their injuries directly to Defendants, and were systematically
 2 ignored. (See Paras. 89-90, *infra*.) On information and belief, anywhere
 3 between dozens and thousands of FasciaBlaster users complained, or
 4 merely inquired, about adverse experiences from 'blasting' on e.g.
 5 social media forums, before Defendants censored or deleted their
 6 comments and questions, and banned them from further participation in
 7 said forums to prevent potential customers from seeing honest feedback
 8 of a negative nature. Plenty of these complaints were raised before May
 9 18, 2017; on information and belief, Defendant Black has received
 10 numerous complaints dating back more than a year before she made
 11 this claim. Many reports were provided to Defendants pertaining to
 12 users whose injuries were serious enough to require emergency
 13 hospitalization, including multiple Plaintiffs herein and others similarly
 14 situated, and as explicitly noted in the FDA Inspection Report of which
 15 Black had full knowledge before publicly claiming otherwise on
 16 August 31, 2017.

17 (e) Defendants have claimed that FasciaBlaster use will not affect
 18 hormones and will not increase estrogen levels. °In fact, the
 19 experiences of multiple Plaintiffs and others similarly situated
 20 demonstrate the dramatic effects FasciaBlaster use has wrought on their
 21 hormone levels, including extreme cramping, missed periods, unusual
 22 menstrual bleeding (e.g. lasting up to 10 days), depression, anxiety, etc.

23 (f) Defendants did and/or do claim that FasciaBlaster reduces the
 24 appearance of varicose veins, and is "100% effective" at treating
 25 cellulite, purportedly "better, faster, and more affordable than
 26 [competing approaches to cellulite reduction] freezing [i.e.
 27 CoolSculpting®] or surgery [e.g. liposuction]." °In fact, after 'blasting'
 28

1 multiple Plaintiffs experienced a marked increase in the appearance and
2 severity of cellulite, varicose and spider veins, and these worsened
3 conditions have persisted long after they ceased 'blasting,' six months
4 later or more.

5 (g) Defendants did and/or do claim that FasciaBlaster erases lines
6 and wrinkles. °In fact, 'blasting' worsened the lines and wrinkles of
7 multiple Plaintiffs and others similarly situated.

8 (h) Defendants have claimed that bruising from FasciaBlaster is
9 "healthy, restorative, and cleansing[,]" and that, at any rate, any such
10 aesthetic side effects of any kind are only temporary and will improve
11 with continued 'blasting' in keeping with Defendant Black's oft-
12 repeated refrain, "worse before better!" °In fact, notwithstanding

13 faithful adherence to Defendants' instructions for use, multiple
14 Plaintiffs and others similarly situated have had the following side
15 effects persist through, and well after, prolonged 'blasting':
16 hemosiderin staining, crêpe skin, loose skin, fallen face, persistent claw
17 lines/rake marks, inflammation, Oxidative stress, crepitus, weight gain,
18 adrenal fatigue, thyroid disruption, hematoma, blood clot, burst blood
19 vessel, hormonal changes, mood swings, depression, anxiety, panic
20 attacks, Vasovagal Syncope, heart palpitations, difficulty breathing,
21 lightheadedness, vertigo, flu-like symptoms, nerve pain, joint pain,
22 muscle pain, muscle spasms, headaches, numbness, chronic Pruritis,
23 itching or burning sensations, rash, chronic perivascular dermatitis,
24 hives, hair loss, viral outbreaks, chest pain, etc.

25 (i) Defendants' various websites and social media profiles feature
26 multiple sets of promising 'before and after' photos to demonstrate the
27 results FasciaBlaster provides. ° Subject to proof: many of the photos
28

1 are digitally altered, others appear to have been copied from various
2 plastic surgery or liposuction websites, and on information and belief,
3 including according to former FasciaBlaster spokesperson Dari Samia,
4 at least one pair of pictures was taken mere moments apart, but with
5 different lighting giving them the appearance of improvement from one
6 to the next. On information and belief, at least one pair of photos
7 feature a woman who was eight-months pregnant in the 'before' photo,
8 then four or five months postpartum in the 'after,' which Defendants
9 fail to disclose in presenting them as indicative of successful 'blasting'.

10 **Fasciablaster's Chemical Composition**

11 85. Plaintiffs are informed and believe, and thereon allege, that
12 FasciaBlaster has been and is dangerous and defective in its design, and unfit to be
13 used for any purpose by any person, and that Defendants have been on actual and
14 constructive notice of said unfitness at all relevant times.

15 86. On information and belief, the chemical composition of the plastic in a
16 FasciaBlaster device includes more than 40% Bisphenol A ("BPA"), which can both
17 mimic and antagonize estrogen in the body. Multiple scientific studies link BPA to
18 endocrine system disruption, dating as far back as 1997. Studies have linked BPA's
19 xenoestrogenic effects to, *inter alia*, metabolic disease, thyroid disruption,
20 neurological damage, interference with fetal and early childhood development,
21 dopaminergic harms (e.g. attention deficits and increased susceptibility to drug
22 addiction), and multiple cancers (most prominently, breast cancer).

23 87. Studies have also demonstrated—and sources including Mayo Clinic
24 and Harvard University School of Public Health warn—that exposure to heat can
25 cause BPA to leach out of plastic at especially dangerous levels.

26 88. Notwithstanding the foregoing, Defendants did and do direct
27 FasciaBlaster users to use copious heat in their 'blasting' routines; each named
28

1 Plaintiff followed such instruction, and ‘blasted’ only during or immediately after a
2 sauna or very hot bath or shower. For example, Plaintiff Lanum used a portable
3 sauna device which was provided to every participant in the putative “clinical trial”
4 at ASPI; Plaintiff Haavisto’s husband built a sauna for her in their home—at
5 substantial expense—specifically for ‘blasting’ purposes when she bought
6 FasciaBlaster; Plaintiff Gaines would always ‘blast’ during a hot shower. On
7 information and belief, tens of thousands of FasciaBlaster users follow Defendants’
8 guidance for use under temperature conditions which dramatically increase the risk
9 of BPA leaching from the device into their skin. Moreover, on information and
10 belief, Defendants’ recommended oils and moisturizers risk further increasing
11 dermal penetrability, i.e. the ease with which a toxin like BPA can slip into the
12 user’s body through her skin.

13 FDA Inspection

14 89. Between July 18 and August 4, 2017, an investigator from the U.S.
15 Department of Health and Human Services (“DHHS”), Food and Drug
16 Administration (“FDA”) found numerous faults with Defendants’ business
17 practices, detailed in Establishment Inspection Report FEI # 3012547534 (“FDA
18 Inspection Report”), which the Plaintiffs submit herewith as “Exhibit A.”

19 Among other things, the FDA Inspection Report reflects the Investigator’s
20 determinations that:

- 21 (a) Defendants had failed to develop, maintain, or implement
22 procedures for Medical Device Reporting (“MDR”) by consumers.
23 (b) Defendants were aware that 70 MDRs had been filed in the
24 preceding year alleging injury by FasciaBlaster, but Defendants had
25 nevertheless failed in every instance to initiate any corrective and
26 preventive procedures (“CAPA”) to address them.
27 (c) Defendants had in fact “failed to define[], document[], or
28

1 implement[] [any] CAPA procedure to analyze, for example, processes,
2 work operations, recurring complaints, returned product and other
3 sources of quality data that identify existing and potential causes of
4 nonconforming product or other quality problems.”

5 (d) Defendants have “been importing their FDA registered, Class I
6 medical device for at least 18 months, beginning initially ... in 2015
7 but there was no evidence that complaints older than 01 month have
8 been evaluated.”

9 (e) The foregoing might be explained in part by the fact that, for
10 every example of a user complaint which the Investigator cites in her
11 report, she notes either that “I found *minimal...*” or “I found *no*
12 *evidence that an attempt was made to determine the relationship, if*
13 *any, of the device to the reported incident or adverse event* to evaluate
14 if it was MDR reportable[,]” or that “I found *no evidence that an*
15 *attempt was made*, after learning the batch number of the medical
16 device, *to determine why* the medical device malfunctioned or if it was
17 due to a failure to meet design specifications.” (Emphasis added.)

18 (f) “Multiple complaints began to come into FDA’s MDR database”
19 as far back as “June 2016” and, the Investigator explicitly makes note,
20 multiple consumers reported requiring hospitalization for their injuries.

21 (g) “The FasciaBlaster and AshleyBlackGuru (websites) appear to
22 make structure/function claims that exceed the limitations of a Class II
23 (*sic*) medical device.”

24 (h) “The website makes disease claims by asserting that the medical
25 device can alleviate the symptoms of specific diseases. For example,

26 Restores Blood flow (cardiovascular disease)

27 Increases Nerve Activity (rheumatoid arthritis)
28